

REMARKS**35 U.S.C. 112, 1st paragraph rejection (New Matter)**

Claims 5-12 and 27-31 were rejected by the examiner as containing new matter for use of the phrase "increasing the synthesis rate of ceramides of human skin". While the applicants appreciate the examiner's reconsideration after their phone message of 23 April 2003, the applicants respectfully disagree with the maintaining of this rejection.

However, in the applicants' previous response, attention was directed towards page 5, fourth paragraph of the specification for support of the limitation represented by claim 29. This paragraph also contained the phrase "increase the synthesis rate of ceramides in human skin in general."

Moreover, the examiner acknowledged that sphingolipids are lipids containing sphingosine. Referring to page 7, first paragraph of the applicants' previous response, it was indicated that ceramides are examples of sphingolipids. A dictionary definition of "ceramide" from Dorland's Pocket Medical Dictionary: any of a group of naturally occurring sphingolipids in which the NH₂ group of sphingosine is acylated with a fatty acyl CoA derivative to form an *N*-acylsphingosine. Again, referring to the relatively low threshold required to meet the written description requirement (and that, while certainly helpful, there is no requirement under 35 U.S.C. 112 for *ipsis verbis* support for the claimed subject matter in the specification), it is unclear what is the basis for the examiner's holding of new matter.

35 U.S.C. 103(a) rejection

Claims 5-12 and 27-31 were rejected as being obvious by the examiner over Znaiden et al. (U.S. Patent 5,523,090).

Clear Error by Examiner Berman Not Established

Before addressing the substance of the rejection, it is noted that the Znaiden et al. reference was previously used in the first office action (Paper No. 6) by Examiner Berman against similarly claimed subject matter and was withdrawn after the arguments presented in the applicants' response of 8 March 2002. MPEP 706.04 states in the subheading "Previous Action by Different Examiner":

"Full faith and credit should be given to the search and action of a previous examiner unless there is clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make new search in the mere hope of finding something."

If the examiner is alleging a clear error has been made by Examiner Berman, the basis for this error has not been articulated by the present examiner.

Anticipation Requires Each Element Be Taught By Prior Art

MPEP 2131 states that to anticipate a claim, the reference must teach every element of the claim and quotes from *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (Fed. Cir. 1989) which states "The identical invention must be shown in as complete detail as is contained in the...claim."

The examiner's recitation of Example 12 of Znaiden et al. which contains epicatechin in a composition, which does not contain an alpha hydroxyl acid, used to treat cellulite and col. 2, lines 13-20, which cites the use of alpha hydroxy acids for a variety of skin conditions, does not establish the inventive concept of the applicants' invention, i.e. the use of catechins and gallic esters of catechins (which are not alpha hydroxyl acids) could be used for treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof.

Therefore, there is no description in Znaiden et al. which teaches "the identical invention in as complete detail as is contained in the ...[applicant's] claim."

NOTE: The compound of claim 7 is not epicatechin; it is catechin (compare with page 4 of specification)

Inherency Requires Extrinsic Evidence

The examiner makes several statements directed toward inherency which might be applicable to a composition claim (see reference to *In re Spada* from MPEP 2112.01 - "When the PTO shows a sound basis for believing that **the products** of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."). However, the applicants are not claiming a composition but a method of using a composition. The Znaiden et al. reference shows no recognition that catechins or gallic

esters of catechins had the effects claimed by the applicants. If the applicants' are alleging inherency between treating cellulite and the treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof, this has not been established by the examiner.

MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).....***To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.*** Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), see also *Mentor H/S, Inc. v. Medical Device Alliance, Inc. (Mentor II)*, 244 F.3d 1365, 58 USPQ2d 1321 (Fed. Cir. 2001) and *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) – bold and italics added by author for emphasis. It is also insufficient to do no more than broadly allege that claim limitations are disclosed in the prior art "either expressly or inherently" as the Federal Circuit noted in *Electro Scientific Industries, Inc. v. General Scanning, Inc.*, 247 F.3d 1341, 58 USPQ2d 1498 (Fed. Cir. 2001).

In the present situation, it cannot even be established that the epicatechin used in Example 12 of Znaiden et al. would even be recognized as the active ingredient to treat cellulite to even have a starting basis to begin the factual determination of inherency.

Anticipation Rejection Presented Does Not Rise to the Level of Clear Error

Even if *in arguendo*, one were to accept that there could be some debate as to whether a rejection based on Znaiden et al. would be appropriate, this does not rise to the level of assigning clear error to Examiner Berman for withdrawing her rejection.

Closing

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any

issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (5 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 1 May 2003

By: Jennifer Archer
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